ANTI-REGURGITATION INFANT FORMULA

This is a continuation-in-part of Ser. No. 08/457,699 filed Jun. 1, 1995 now abandoned.

FIELD OF INVENTION

The present invention concerns infant formula thickened with a potato starch or waxy starch which contains a high level of amylopectin.

BACKGROUND OF INVENTION

Starch is composed of two distinct polymer fractions: amylose and amylopectin. Amylose is the linear fraction consisting of α-1,4 linked glucose units. Amylopectin has the same structure as amylose but some of the glucose units are combined in an α-1,6 linkage giving rise to a branched structure. Starches generally contain 17–24% amylose and from 76–83% amylopectin.

Special genetic varieties of plants have been discovered or developed which produce starch with unusual amylose to amylopectin ratios. Some plants produce starch that is free of amylose. These mutants produce starch granules in the endosperm and pollen which stain red with iodine and which contain nearly 100% amylopectin. Predominant among such amylopectin producing plants are waxy corn, waxy sorghum and waxy rice starch.

Regurgitation of infant formula by infants is a common problem. The addition of certain thickening agents to infant formulas is known in the art to be effective in reducing the incidence and/or severity of regurgitation. Examples of thickening agents known in the art include rice cereal (see, Ramenofsky, M. L., et al, *J. Pediatr. Surg,* 1981; 16:374–378) and seed gums like carob bean gum (see, Vandenplas, Y., et al, *Clin. Pediatics,* 1987; 26(2):66–68; European Patent 0611524).

Commercial products are Frisovom from Friesland Frico Domo and Nutrilon AR from Nutricia which contain locust bean gum as a thickening agent.

It has been discovered that use of potato starch or certain high amylopectin containing grain starches in infant formulas provides advantages heretofore unachievable.

SUMMARY OF INVENTION

The present invention is directed to an infant formula comprising a thickening agent which comprises potato starch, waxy grain starch, or mixtures thereof in an amount effective to ameliorate regurgitation in infants.

In another aspect, the present invention is directed to a method for treating regurgitation in an infant in need of treatment comprising administering to said infant an effective amount of the infant formula of the invention.

DETAILED DESCRIPTION OF INVENTION

The present invention provides an infant formula thickened with certain food starches for the management of postprandial gastroesophageal reflux ("GER", commonly referred to as "regurgitation"). To thicken the infant formula, starches derived from the following sources can be used alone or in combination: potato starch or waxy grain starch. The infant formula so thickened has been found to be advantageous in the treatment of regurgitation.

The starches can be used in their native state or with additional pre-treatments such as pregelatinization or agglomeration to facilitate ease of use. By the term "waxy" it is meant an appropriate starch which contains at least about 90% amylopectin by weight. Preferred waxy starches contain at least about 95% amylopectin and more preferred starches contain at least about 98% amylopectin by weight.

Preferred waxy starches are waxy corn, waxy rice and waxy sorghum. More preferred are waxy corn and waxy rice, and most preferred is waxy rice.

Waxy corn starch has an amylopectin content of approximately 99%. Rice flour has slightly lower viscosity than rice starch for non-waxy samples; however, twice as much waxy rice flour is needed to obtain the same viscosity as given by waxy rice starch. Waxy rice starch has 98–100% amylopectin. Rice has one of the smallest starch granules of the cereal starches, varying in size from about 3–10 micrometers (μm) in the mature grain. Mean granule size varies from about 4–6 μm. Potato starches have generally larger granules than the grain starches, e.g., about 30–50 μm. When cooked, the large swollen granules impart extra high viscosity.

Prior art formulas using rice cereal as a thickening agent become hypercaloric. Such prior art formulas can have caloric densities of up to 30 Calories per fluid ounce (Cal./fl. oz.). In contrast, the formula of the invention is not hypercaloric, i.e., has a caloric density of not more than 24 Cal./fl. oz., preferably not more than 20 Cal./fl. oz. The present invention specifically contemplates formulas having a caloric density greater than 20 Cal./fl. oz. and not more than 24 Cal./fl. oz.

Rice cereal or gums could also make the formula too thick so that the infant would have to work hard at sucking out of the normal hole in a bottle nipple. This is usually remedied by cutting bigger holes in bottle nipples but could cause the formula to flow too quickly, which may lead to choking and tongue thrusting in an infant already at risk for oral motor dysfunction. Moreover, rice cereal is not soluble and has a tendency to settle, resulting in instability upon storage. Rice flour has slightly lower viscosity than rice starch for non-waxy samples; however, twice as much waxy rice flour is needed to obtain the same viscosity as given by waxy rice starch.

The performance of starches of the invention under conditions of heat, shear and acid may be improved by chemical modifications. Modifications are usually attained by introduction of substituent chemical groups. Viscosity at high temperatures or high shear can be increased or stabilized by cross-linking with di- or polyfunctional reagents such as phosphorus oxychloride.

In some instances, it is preferred that the starch of the invention is pregelatinized. Pregelatinization of starch is a process of precooking starch to produce material that hydrates and swells in cold water. Drum drying is the most common method of preparation. The feed starch can be a chemically modified product to further extend the range of finished properties.

Native starch granules are insoluble in water but when heated in water, the granule begins to swell when sufficient heat energy is present to overcome the bonding forces of the starch molecules. With continued heating, the granule swells